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10/529,636	03/31/2005	Hans-Ulrich Petereit	268018US0PCT	1376
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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER WELTER, RACHAEL E	
			ART UNIT	PAPER NUMBER
			1611	
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			09/19/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/529,636	<b>Applicant(s)</b> PETEREIT ET AL.	
	<b>Examiner</b> RACHAEL E. WELTER	<b>Art Unit</b> 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☒ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/19/08 &amp; 5/6/08</u> .                                    | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Acknowledgments***

The examiner acknowledges receipt of applicant's amendment and response filed 1/30/08 to the non-final rejection filed 12/3/07.

**Claim Status:** *Claims 14-32 are pending.*

### ***Information Disclosure Statements***

The information disclosure statements (IDS) submitted on February 19, 2008 and May 6, 2008 were in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. A signed copy of forms 1449 are enclosed herewith.

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. No English translation of the Certified Copy of the Foreign Priority Application has been received.

### ***Specification***

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Claim Objections***

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Claim 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 23 fails to further limit the subject matter of independent claim 14 from which it is dependent. Claim 23 refers to the same method "utilizing one or more spray devices" and claim 14 also refers to a spray application "using one or more spray devices" in line 20 of the claim. Therefore, claim 23 fails to further limit the subject matter of claim 14 from which it is dependent.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-32 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The means for mixing of incompatible polymers, critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA, 1976).

Claim 14 is drawn to a method for producing a pharmaceutical dosage form "...in such a way that the incompatible individual portions are mixed in the spraying process," and claims 15-32 depend either directly or indirectly therefrom. Applicant recites that this incompatibility of the instant acrylate copolymers results in "aggregation or

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coagulation" (Specification page 3, lines 9-11) such that the "mixture cannot at present be employed industrially in an acceptable manner" (Id. at lines 13-14). The critical steps represented by the phrase "in such a way" are not further elucidated, thus the disclosure is not enabling.

### ***Response to Arguments***

The above rejection was not overcome by the amendment submitted on 12/3/07. Applicant only amended claim 14 to state that the coating agents were incompatible when mixed. It is still not clear how the incompatible coating agents, which aggregate and coagulate when mixed, are employed industrially in this invention with reasonable experimentation. Thus, the rejection is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims are rejected as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 14 and the claims dependent from it refer to the first film-forming coating and second film-forming coating agent as being incompatible when mixed together in an aqueous solution or dispersion. However, claim 14 and the claims dependent from it also state that the coating agents are mixed in the spraying process.

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In the specification, applicants recites that the incompatibility of the coating agents results in aggregation or coagulation (pg. 3, lines 9-11). Therefore, the omitted steps should describe mixing of the coating agents such that aggregation or coagulation is avoided, resulting in an industrially useful process for coating.

Claim 15 is further rejected because it contains the word "especially."

"Especially" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). In addition, claim 15 contains the phrase, "and/or." This phrase renders the claim indefinite because it is unclear whether it comprises both components or either one of the components.

Claim 22 is further rejected because it refers to the spray application taking place by "means of spray devices as fixed installation." It is unclear from the prior art, specification, and claims what the term "fixed installation" means. This undefined term appears to be a literal translation into English from a foreign document.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulye (US 2002/0192285) in view of Pinoit et al (*Polymer* 43:2321-2328).

Claims 30-32 are drawn to pharmaceutical forms produced by the method for producing a coated pharmaceutical form. Since this is a product-by-process limitation, determination of the patentability is based on the product itself. In this case, the product must comprise a first film-forming coating agent, a (meth)acrylate copolymer of 30-80 wt.% or 70-20 wt.% (meth)acrylate monomers having a tertiary amino group in the alkyl radical. Furthermore, the product must comprise a second film-forming coating agent that is a polymer having anionic groups. Moreover, the coating agents should comprise no more than 20 wt.% plasticizer and no more than 5 wt.% of nonionic emulsifier. Finally, the first film-forming coating agent and the second film-forming coating agent are incompatible in aqueous dispersion or solution of the two different coating agents.

Mulye teaches an aqueous pharmaceutical coating formulation which is used for coating core elements containing one or more medicaments to achieve controlled release (abstract). Mulye teaches that the core elements contain medicaments, such as vitamins, antiarrhythmics, anti-inflammatory drugs, etc (paragraph 0054-0055). The first

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component of the coating composition is a water insoluble polymer which includes methacrylic ester polymers and polymers or copolymers of acrylates or methacrylates (paragraph 0037). The insoluble polymer comprises at least 75 wt.% of the coating (paragraph 0038). In addition, the coating formulation contains an enteric polymer, which can be selected from polyvinyl acetate phthalate (PVAP) and a methacrylic acid copolymer (paragraph 0040). The coating composition can contain plasticizers (paragraph 0047), which are most preferably from 0.1-10 wt.% (paragraph 0062) of the core element. In addition, the coating composition comprises nonionic emulsifiers like polyalkylene glycol and polyethylene glycol, which are present from 0.1-5 wt% of the core element.

Muyle fails to teach that the coating agents like PVAP and methacrylic copolymer are incompatible when mixed together in an aqueous solution or dispersion. In addition, Muyle does not teach the specific amount of (meth)acrylate copolymer of the instant claims, 30-80 wt.%. Instead, Muyle teach at least 75 wt.% of the polymers or copolymers of acrylates or methacrylates.

Pinoit et al teach the phase behavior of ternary blends of poly (methyl methacrylate) (PMMA) and poly(vinyl acetate) PVAc) (abstract). According to Pinoit et al, PVAc and PMMA are an immiscible polymer pair and incapable of forming a single homogeneous phase (abstract; introduction).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to mix the immiscible coating agents as evidenced by Pinoit et al. Pinoit et al is relied upon to show that the two coating agents are incompatible. One



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would have been motivated to do so in order to obtain a desired controlled release of a pharmaceutical agent comprising the coating agents.

Moreover, it would have been obvious to an artisan of at the time the invention was made to optimize the amount of methacrylate copolymer. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonable expect success. One would have been motivated to determine the optimal methacrylate copolymer amount in order to best achieve the desired results. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) & *MPEP* 2144.05.

Claims 14-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulye (US 2002/0192285) in view of Murphy (US Patent No. 3,296,016) and Pinoit et al (*Polymer* 43: 2321-2328).

Claims 14-29 are drawn to a method for producing a coated pharmaceutical form comprising coating a substrate with a mixture of two film-forming coating agents. The first film-forming coating agent is (meth)acrylate copolymer of 30-80 wt.% or 70-20 wt.% (meth)acrylate monomers having a tertiary amino group. The second film-forming coating agent is a polymer having anionic groups, which is preferably a cellulose derivative, a polyvinyl acetate derivative, or a (meth)acrylate copolymer. However, the coating agents contain no more than 20 wt.% of plasticizer or 5 wt.% of nonionic emulsifier. The coating agents are incompatible when mixed in an aqueous solution or dispersion and are simultaneously sprayed by spray application using one or more

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spray devices, which singly or together, atomize liquids separately, and whose spray beams overlap. The coating agents are mixed in the spray process and the mixture impinges on the substrate producing a film coating. The coating agents comprise customary additives like plasticizers and/or an active pharmaceutical ingredient. The substrate is selected from active ingredient crystals, cores, tablets, granules, pellets, etc (claim 16). The first film-forming coating agent is a copolymer of 25 wt.% methyl methacrylate, 25 wt.% butyl methacrylate and 50 wt.% dimethylaminoethyl methacrylate. The film forming coating agents are present in a ratio of 9:1-1:9 based on the total polymer content of the film coating. Two or more two-fluid nozzles or one or more three-fluid nozzles are employed as a spray device. The spray application takes place in a drum coater, a coating pan, etc (claim 21) and utilizes two or more spray devices. The total amount of the first and second film-forming coating agents is more than 5 wt.% based on the weight of the uncoated substrate. Furthermore, in light of the 112, 2<sup>nd</sup>, the examiner interprets claim 22 to be directed to a spray nozzle in a fixed position.

Mulye teaches an aqueous pharmaceutical coating formulation which is used for coating core elements containing one or more medicaments to achieve controlled release (abstract). The first component of the coating composition is a water insoluble polymer which includes methacrylic ester polymers and polymers or copolymers of acrylates or methacrylates (paragraph 0037). The insoluble polymer comprises at least 75 wt.% of the coating (paragraph 0038). In addition, the coating formulation contains an enteric polymer, which can be selected from polyvinyl acetate phthalate (PVAP) and

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a methacrylic acid copolymer (paragraph 0040). The coating polymers are present in the coating composition in a weight ratio ranging from about 3:1-20:1 (paragraph 0042) and the coating composition is preferably 3-15 wt.% of the core (paragraph 0052). The coating composition can contain plasticizers (paragraph 0047), which are most preferably from 0.1-10 wt.% (paragraph 0062) of the core element. In addition, the coating composition comprises nonionic emulsifiers like polyalkylene glycol and polyethylene glycol, which are present from 0.1-5 wt% of the core element. Furthermore, the central core can be in the form of a pellet, seed, bead, or sphere (paragraph 0065-0066). Moreover, Muyle teaches that the spray coating of the core element can be undertaken using bottom, top, or tangentially located spray nozzles in a fixed position (paragraph 0075). Various coating apparatuses may be employed including a fluidized bed coating apparatus, a pan coating apparatus, etc (paragraph 0078). Muyle does not teach that the coating agents are simultaneously sprayed using one or more spray devices which singly or together, atomize liquids separately and whose spray beams overlap. In addition, Muyle does not teach that the coating agents are mixed in the spraying process, resulting in the mixture impinging on the substrate and producing a film coating. Furthermore, Muyle fails to teach that the coating agents like PVAP and methacrylic copolymer are incompatible when mixed together in an aqueous solution or dispersion.

Murphy teaches a process for producing microporous films and sheets of polymeric materials in conjunction with a substrate layer (column 1, lines 10-13). According to Murphy, two sprays of polymer in solvent and polymer nonsolvent are

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directed so that they combine and overlap at or before striking the substrate (column 3, lines 8-10). Murphy teaches that it is preferable to not mix the fluids before they reach the spray nozzles and that two sprays from separate nozzles should not be mixed (column 3, lines 16-23). According to Murphy, if the sprays are combined too quickly, coagulation can occur creating an undesirable, less uniform coating (column 3, lines 23-45).

Pinoit et al teach the phase behavior of ternary blends of poly (methyl methacrylate) (PMMA) and poly(vinyl acetate) PVAc) (abstract). According to Pinoit et al, PVAc and PMMA are an immiscible polymer pair and incapable of forming a single homogeneous phase (abstract; introduction).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to mix the immiscible coating agents as evidenced by Pinoit et al and taught in Muyle within the spray beams right before striking the substrate. Pinoit et al is relied upon to show that the two coating agents are incompatible. One would have been motivated to mix the incompatible polymers within the spray beams right before striking the substrate in order to avoid coagulation and create a more desirable, uniform coating.

Moreover, it would have been obvious to an artisan of ordinary skill at the time the invention was made to use two or more spray devices. The utilization of two spray devices doubles the amount of flow and increases the amount of coating that can be sprayed onto a substrate versus using only one spray device. Therefore, one would

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have been motivated to manipulate the spraying device setup and maximize the flow and amount of coating that could be sprayed onto a substrate.

### ***Response to Arguments***

Applicant's arguments filed 2/1/08 have been fully considered but they are moot in view of the new grounds for rejection presented above.

### ***Conclusion***

Claims 14-32 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611